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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
EDEN PRAIRIE, MN 55344

EXAMINER	
SEVERSON, RYAN J	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,675	MCHALE ET AL.	
	Examiner	Art Unit	
	Ryan J. Severson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 58-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26 and 58-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. **Claims 1, 5, 6, 18-20 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Wolvek et al. (4,276,874).** Matthews et al. disclose a catheter (see figure 6) having a shaft and a balloon (60) mounted thereon. The shaft has a distal portion, a central portion, and a proximal portion all having the same cross-sectional areas. First and second recessed portions (64 and 66) separate the distal, central, and proximal shaft portions. A radiused tip (65) is at the end of the shaft. However, Matthews et al. do not disclose the recessed portions extend around the periphery of the catheter tip. Attention is drawn to Wolvek et al., who teach recessed portions (for example, 38) extending around the periphery of the shaft. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the openings (recessed portions) of Matthews et al. extend around the periphery of the tip in the manner taught by Wolvek et al. Such a combination is merely a combination of known prior art elements. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

3. **Claims 2-4, 7-10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Wolvek et al. (4,276,874) as applied to claim 1 above, and further in view of Fulton (6,074,374).** The combination of Matthews et al. and Wolvek et al. does not disclose a marker or hub disposed beneath the balloon. Attention is drawn to Fulton, who teaches a marker or hub (69) is disposed beneath the balloon to allow the balloon to be place in the body in the correct place (centered at the treatment site) using well-known visualization techniques. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the marker hub of Fulton on the shaft beneath the balloon of the combination of Matthews et al. and Wolvek et al. to allow to correct placement of the catheter and balloon at the treatment site.

4. **Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Wolvek et al. (4,276,874) and Fulton et al. (6,074,374) as applied to claim 9 above, and further in view of Follmer et al. (5,728,065).** The combination of Matthews et al., Wolvek et al., and Fulton et al. does not disclose a marker disposed flush with the outer surface of the catheter tip. Attention is drawn to Follmer et al., who teach a radiopaque marker (124) insert molded flush with the tip (see figure 2) to create a tip that has a low profile and can be imaged because the marker does not project radially outwardly from the tip. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to insert mold flush the marker of Follmer et al. with the tip of the combination of Matthews

et al., Wolvek et al., and Fulton to create a tip that has a low profile yet can be located and guided using conventional imaging techniques.

5. **Claims 12, 13, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Wolvek et al. (4,276,874) as applied to claim 1 above, and further in view of Follmer et al. (5,728,065).** The combination of Matthews et al. and Wolvek et al. does not disclose a first region and second region having differing flexibilities. Attention is drawn to Follmer et al., who teach a catheter tip may have two regions (122 and 114) with the second region (spring 114) being less flexible than the first region due to the reinforcements therein (see column 7, lines 9 and 10), which creates a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device with losing the flexibility in the tip. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the tip of the combination of Matthews et al. and Wolvek et al. of two regions wherein the first region is more flexible than the second region, as taught by Follmer et al., to create a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device with losing the flexibility in the tip.

6. **Claims 16 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Follmer et al. (5,728,065) and Chee et al. (5,906,606).** Matthews et al. disclose a catheter (see figure 6) having a shaft and a balloon (60) mounted thereon. The shaft has a distal portion, a central portion, and a proximal portion all having the same cross-sectional areas. First and second recessed

portions (64 and 66) separate the distal, central, and proximal shaft portions. A radiused tip (65) is at the end of the shaft. However, Matthews et al. do not disclose a first region and second region having differing flexibilities. Attention is drawn to Follmer et al., who teach a catheter tip may have two regions (122 and 114) with the second region (114) being less flexible than the first region due to the reinforcements therein (see column 7, lines 9 and 10), which creates a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device with losing the flexibility in the tip. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the tip of Matthews et al. of two regions wherein the first region is more flexible than the second region, as taught by Follmer et al., to create a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device with losing the flexibility in the tip.

7. Further, the combination does not disclose the second region is made of stiffening fibers of polypropylene or polyolefin. Attention is drawn to Chee et al., who teach a catheter tip may be reinforced with non-metallic materials (see column 7, lines 32-34) to create a device that has the rigidity desired yet is lightweight. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the fibers of the combination of Matthews et al., Follmer et al., and Chee et al. of polypropylene fibers or polyolefin fibers, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

8. **Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Wolvek et al. (4,276,874) as applied to claim 1 above, and further in view of Imran et al. (5,766,203).** The combination of Matthews et al. and Wolvek et al. does not disclose the catheter is a stent delivery catheter. Attention is drawn to Imran et al., who teach a balloon catheter can be used to deliver a stent to provide permanent support to a weakened vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the catheter of the combination of Matthews et al. and Wolvek et al. as a stent delivery catheter, as taught by Imran et al., to deliver a stent to provide permanent support to a weakened vessel.

9. Regarding claim 22, Imran et al. teach a stent mounted about the balloon (see figure 8C).

10. Regarding claim 23, the stent of Imran et al. is an inflation expandable stent (see column 8, lines 36-41).

11. Regarding claim 24, the Imran et al. stent is self-expanding (column 8, line 56).

12. **Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Wolvek et al. (4,276,874) as applied to claim 1 above, and further in view of Hamilton et al. (6,514,228).** The combination of Matthews et al. and Wolvek et al. does not disclose the catheter tip is shaped like a triangle. Attention is drawn to Hamilton et al., who teach an inner catheter tip may have a triangular cross section if desired. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to shape the tip of the

combination of Matthews et al. and Wolvek et al. in a triangular shape, as taught by Hamilton et al., as an obvious alternative to the circular catheter shape.

13. **Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Wolvek et al. (4,276,874) and Follmer et al. (5,728,065) as applied to claim 15 above, and further in view of Chee et al. (5,906,606).** The combination of Matthews et al., Wolvek et al., and Follmer et al. does not disclose the second region comprises stiffeners that are carbon fibers. Attention is drawn to Chee et al., who teach a catheter tip may be reinforced with carbon fibers (see column 7, lines 32-34) to create a device that has the rigidity desired yet is lightweight. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the carbon fibers of Chee et al. to replace the metallic ribbons of Follmer et al. as the reinforcements in the second region to create a device that has the rigidity desired in the second region but reduces the weight of the device by using the carbon fibers instead of larger ribbons.

Response to Arguments

14. Applicant's arguments filed 12/12/2008 with respect to claim 16 have been fully considered but they are not persuasive. Applicant argues the combination is improper because the Matthews et al. and Follmer et al. devices perform different functions. However, the functions of the catheters have not been relied upon for the rejection. The prior art clearly shows all of the claimed limitations. The combination of the art in the two references is merely a combination of known prior art elements. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

15. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

17. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. J. S./
Examiner, Art Unit 3731
4/7/09

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731